

TENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: FASKEN MARTINEAU DUMOULIN LLP 2100 - 1075 West Georgia Street VANCOUVER, British Columbia Canada, V6E 3G2		<div style="text-align: center;"> PCT WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1) </div>																	
Applicant's or agent's file reference 260625.00005		FOR FURTHER ACTION See paragraph 2 below																	
International application No. PCT/CA2005/000412	International filing date (day/month/year) 18 March 2005 (18-03-2005)	Priority date (day/month/year) 18 March 2004 (18-03-2004)																	
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61L 9/015, A61L 2/20, C01B 13/11																			
Applicant TREATED AIR SYSTEMS INC. ET AL																			
<p>1. This opinion contains indications relating to the following items :</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;"><input checked="" type="checkbox"/> Box No. I</td> <td>Basis of the opinion</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/> Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. V</td> <td>Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/> Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> <p>2. FURTHER ACTION If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.</p> <p>If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.</p> <p>For further options, see Form PCT/ISA/220.</p> <p>3. For further details, see notes to Form PCT/ISA/220.</p>				<input checked="" type="checkbox"/> Box No. I	Basis of the opinion	<input checked="" type="checkbox"/> Box No. II	Priority	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/> Box No. VI	Certain documents cited	<input checked="" type="checkbox"/> Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/> Box No. VIII	Certain observations on the international application
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Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001(819)953-2476		Date of completion of this opinion 7 June 2005 (07-06-2005)																	
Authorized officer <div style="text-align: center;">Okemona Oke (819) 956-4108</div>																			

Box No. I **Basis of this opinion**

1. With regard to the **language**, this opinion has been established on the basis of:

 ☒ the international application in the language in which it was filed

 ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of :
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search.
- 3 ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statement that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments :

Box No. II

Priority

IAP9/Rec'd PCT/PTO 18 SEP 2006

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1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary :

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☐ not paid additional fees

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with
- ☒ not complied with for the following reasons :

The subject matter of claims 1 and 2 lack any technical feature that defines a contribution over the prior art. The special technical features of claims 1 and 2 reside in a sterilization method and apparatus in a closed humidified environment using ozone. This subject matter already comprise part of the state of the art, and thus cannot be a linking feature to claims 3-4. Further, the special technical features of claims 3 and 4 reside in a method for inactivating Norwalk virus in a closed environment by exposure to 20-30 ppm of ozone for a period of 30-70 minutes, where the humidity of the environment may be elevated. There is no common inventive concept linking the special technical features defined in claims 1 and 2 with those of claims 3 and 4. Thus, the present application is considered to comprise the following group of inventions:

- A. The subject matter of claims 1 and 2
- B. The subject matter of claims 3 and 4

4. Consequently, this opinion has been established in respect of the following parts of the international application :

- ☒ all parts
- ☐ the parts relating to claim

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 3-4	YES
	Claims 1-2	NO
Inventive step (IS)	Claims	YES
	Claims 1-4	NO
Industrial applicability (IA)	Claims 1-4	YES
	Claims	NO

2. Citations and explanations :

The following documents are considered as relevant:

D1: ISHIZAKI, ET AL: "Inactivation of Bacillus spores by gaseous ozone"

The Journal of Applied Bacteriology 1986 60(1), 67-72

D2: MAZAOKA, ET AL: "Ozone Decontamination of Bioclean Rooms"

Applied Environmental Microbiol. 1982 43(2), 509-513

D3: CA 2311386

D4: CA 2270512

D5: CA 2120628

D6: CA 2459041

D7: JP 2001286542 A2

D8: US 5501844

D9: ELFORD, ET AL: "An investigation of the merits of ozone as an

aerial disinfectant" *Journal of Hygiene* 1942, 42, 240-265

D10: US 5368816 B2

D11: SHIN, ET AL: "Reduction of Norwalk virus, Poliovirus 1, and

Bacteriophage MS2 by ozone disinfection of water"

Applied Environmental Microbiol. July 2003, 69(7), 3975-3978

D12: KESWICK, ET A: "Inactivation of Norwalk virus in drinking

water by chlorine" *Applied Environmental Microbiol.* August 1985, 50(2), 261-264

D13: VAUGHN, ET AL: "Inactivation of human and simian

rotaviruses by ozone" *Applied Environmental Microbiol.*,

1 September 1987, 53(9), 2218-2221

D14: SATO, ET AL: "Virucidal effect of ozone treatment of

laboratory animal viruses" *Jikken Dobutsu, Experimental Animals*

April 1990, 39(2), 223-229

D15: BOLTON, ET AL: "Biological effects of ozone aerosols on five

groups of animal viruses" *Abstracts of the annual meeting of*

the American Society of Microbiology. Meeting 1980, vol. 167, page 280, Q89 (see continuation of Box V in Supplemental Sheet)

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted :

The http internet addresses provided in pages 6, 18, 21 and 25 (Figure 4.1) in the Appendix of the description are not static electronic files. The information disclosed in said files is apt to change, is not accessible or retrievable at all times and without restrictions, and is therefore not reliable (Article 5 PCT).

Certain terminologies are employed in a sense that creates confusion, for example, the use of Figures 2-3, which appear in both the first portion of the description, at pages 3, 5, 7 as well as in pages 20 of Appendix A. Applicant should amend the description to remove unnecessary overlap of terminology.

The present description is not conformable with Rules 11 and 26.3(a)(I) PCT:

- pages 5, 21, 22, 23, 26 and 30 of the Appendix A do not admit of direct reproduction;
- the numbering of the pages , in particular, Appendix A, is not consecutive with the first portion of the description;
- the typing in Appendix A is not 1.5-spaced;
- the description, at pages 2, 20, and 25, comprise drawings (Figures 2-4);
- the drawing at page 25 of the Appendix A contain text matter which is adjudged unnecessary;
- pages containing the Figures (excluding those contained within Appendix A) are not numbered in consecutive Arabic numerals.

Applicant should remove certain portions of the description, such as third party comments or observations in pages 2, 29, 30 which are clearly irrelevant to the understanding of the description (Rule 5.1 and Rule 9.1 (iv) PCT).

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made :

Claim 1 does not comply with Article 6 PCT. The expression "sterilizing a closed environment" is avoidably vague and ambiguous. The language creates an unnecessary and troublesome interpretation as to its scope and meaning, and does not accurately reflect the subject matter for which protection is sought. It is not clear, for example, whether said sterilization is targeted at pathogens or just air in the environment. To the extent that the scope of protection sought is rendered limitless by the vague and ill-defined term "sterilizing a closed environment", claim 1 is broader than the invention as described.

Claim 2 does not comply with Article 6 PCT. The underlined terms in the expression "detectinghumidity of a close environment" do not convey a distinct and unambiguous connotation.

Claim 2 does not comply with Article 6 PCT. The term "ozone generator" in the preamble of the claim conflicts with the term "ozone generating means" employed in the characterizing part. This attempts to give both broad and narrow meanings to the scope of protection sought.

The functional relationship between the various components of the ozone generator of claim 2 is not specified, thus the inventive scope is obscure (Article 6 PCT).

Claim 3 does not comply with Article 6 PCT. The term "a quantity" is imprecise, of indeterminate scope and calls for subjective interpretation on the part of the reader.

Claim 3 does not comply with Article 5 PCT. There is no factual support for the claimed method for inactivating a quantity of Norwalk Virus, much less in relation to the specified ozone concentration and specified period of time. An extrapolation of the observed results for Feline Calicivirus (FCV) to Norwalk virus is considered, at best, conjectural and has no factual basis in the description.

Claim 4 does not comply with Article 6 PCT. The term "elevated" is avoidably ambiguous. It is not specified a basis for evaluating what constitutes "elevated".

The reference to personal communication in page 24 is not permitted as a document source since this cannot be independently verified and retrieved (Article 5 PCT).

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Box V**

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Novelty and Inventive Step (Rule 43bis.1 (a)(I) and Article 33(2-3) PCT)

Claims 1-2 relate to an apparatus and process for sterilizing a closed humidified environment in the presence of ozone. These claims lack an inventive step and are not novel in view of the disclosures of D1 - D10. The prior art describes methods and apparatus for sterilization utilizing exposure of ozone in a closed or sealed humidified environment. More particularly, is taught, a method and ozone generator comprising a humidifier (ref char K fig. 1 of D1; page 510 col 2 of D2; ref chars 17, 92 & 96 of D3; page 12 line 18 of D5; ref char 106 of D6; ref char 4 of D7; page 244 third para; col 3 line 3 in D10.), timing means (page 13 line 24-25 of D3; ref char 102, Fig. 4, PLC 100 of D4; ref char 11, page 18 line 29-32 of D5; ref char 92 of D8; ref char 9 in D10), ozone generation means (ref char E in Fig. 1 of D1; ref chars 12 & 22 of D3; ref char 103 of D6; ref char 36 of D8; page 244, second para; ref char 7 in D10.), ozone depleting means (ref char L Fig. 1 of D1; ref char 19 of D3; page 8 line 1-9 of D4; ref char 117 of D5; ref char 12 in D10), movement means (ref char I in Fig. 1 of D1; page 509 right col line 10 of D2; ref char 27 of D3; ref char 70 of D8; page 244 second para of D9; ref char 2 in D10), signalling means (page 14 line 4-5 of D3; Fig. 4 PLC 119 of D4; page 17 line 25, ref chars 73A, 73B & 75 of D5; ref char 84 of D8; col 4 lines 2-12 in D10) and detections means for ozone concentration and humidity (ref chars C & D Fig. 1 of D1; page 509 right col line 22-24, ref char 110 of D4; ref 110 in Fig. 1 of D6, ref 6 of D7, page 244 third para. and page 245 of D9; ref char 8 in D10). The prior art does not explicitly disclose a process for inactivating Norwalk Virus by exposure to ozone in a closed environment, using an ozone concentration and for a period of time as specified in present claim 3, and in the presence of a humidified environment, as claimed in present claim 4. Thus, it would appear the requirement for novelty is met for present claims 3-4.

The technical problem to be solved by the present application is the provision of an alternate disinfectant for Norwalk virus. This is solved, as claimed in present claims 3-4, by exposure of the virus to a closed environment containing having 20-30 ppm of ozone for a period of 30-70 minutes (claim 3), and further, in the presence of elevated humidity (claim 4). Documents D11-D15 represent the closest prior art. D11 describes the disinfection of water contaminated with Norwalk virus by exposure to 0.37 ppm of ozone in a closed reactor for less than 5 minutes (see top of Fig. 2, DISCUSSION lines 1-2). D12 describes the inactivation of norwalk virus in drinking water by chlorine (10 ppm for 10 minutes). D13 describes the inactivation of simian rotavirus SA-11 and human rotavirus type 2 by exposure to ozone at 0.25 ppm and taught that little difference was observed in rotavirus-inactivating efficiencies compared with chlorine as a disinfectant. D14 describes the inactivation of viral pathogens of laboratory animals in a closed environment (closed rooms, animal rooms, safety cabinet) by exposure to ozone of concentration ranging from 0-300 ppm for 1 h in the presence of 80% humidity. D15 discloses the inactivation of a wide range of animal viruses by controlled exposure to humidified ozone (0.16 and 0.64 ppm) environment for 36 to 48 hours. These documents, in combination, clearly teach the use of ozone, having a concentration from as low as 0.16 ppm to as high as 300 ppm, and for a time period ranging from 5 minutes to 2 days, in a closed humidified environment, for effectively and efficiently inactivating a panoply of viruses, including water-borne rotaviruses and Norwalk virus. The presently claimed ozone concentration and exposure time period, therefore, are well within the experimental parameters from which a skilled person in the art would select during routine investigation and merely represent an obvious selection from the range so disclosed by the prior art.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Box V**

In any event, it is not shown that a surprising and superior effect or outcome results from the selected parameters of the present invention compared to the state of the art, as such an inventive step cannot be acknowledged for present claims 3-4.

Industrial Applicability (Rule 43bis.1 (a)(I) and Article 33(4) PCT)

The subject matter of present claims 1-4 appear to meet the requirements for industrial applicability.